This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

THIS PAGE BLANK (USPTO)

OIPE JC177
APR 23 2002
PATENT & TRADEMARK OFFICE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that by virtue of a change of name registered under the Patents Act 1977, the application is now proceeding in the name as substituted.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed R. Mahoney

Dated 5 NOV 2001

THIS PAGE BLANK (USPTO)

GB0027700.4

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of

BENOIST GIRARD SAS, Incorporated in France,
203 Boulevard de la Grande Delle B.P.8,
14201 Herouville-Saint-Clair Cedex,
France

[ADP No. 08098337001]

THIS PAGE BLANK (USPTO)

Patents Form 1/77

Patents Act 1977
(Rule 16)

THE PATENT OFFICE
13 NOV 2000
RECEIVED BY HAND

The Patent Office

14NOV00 E603450-2/002624
P01/7700 0.00-0027700.4

1/77

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

SECTION 30 (1977 ACT) APPLICATION FILED 3/7/00

The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference

AJBB/SPY/H.98

2. Patent application number
(The Patent Office will fill in this part)

13 NOV 2000

0027700.4

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

BENOIST GIRARD ET CIE
203, Boulevard de la Grande Delle - B.P.8.
14201 Hérouville-Saint-Clair Cédex,
France.

Patents ADP number *(if you know it)*

07325855001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

APPARATUS FOR USE IN RESECTIONING A FEMUR WHEN PERFORMING TRANSFEMORAL OSTEOTOMY

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

A.J. BRIDGE-BUTLER

G.F. REDFERN & CO.
7 Staple Inn,
Holborn,
London WC1V 7QF

Patents ADP number *(if you know it)*

1412002

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	11
Claim(s)	
Abstract	
Drawing(s)	4 + 4

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 13 November 2000

12. Name and daytime telephone number of person to contact in the United Kingdom: A.J. BRIDGE-BUTLER 020 7242 7680

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

f) For details of the fee and ways to pay please contact the Patent Office.

APPARATUS FOR USE IN RESECTIONING A FEMUR WHEN PERFORMING TRANSFEMORAL OSTEOTOMY

This invention relates to apparatus for use in resectioning a femur when performing transfemoral osteotomy. In this surgical technique the femur is exposed along a proximal/distal line, the soft tissue (skin, muscle) being folded back on each side to expose the bone. The proximal end of the femur is now open as a "window" and a femoral prosthesis is inserted into the bone canal.

The technique requires careful pre-operative planning, usually from X-rays, and it is possible to calculate in advance how far to cut the "window" so that the distal edge of the "window" end can become a datum base.

There are difficulties and disadvantages when using this technique due to the possibilities of seriously damaging the soft tissue when resectioning the bone. The soft tissue has to be opened along a proximal/distal line and the bone then cut along the same line. This is usually done with a saw but it will be appreciated that the cutting of the soft tissues above the saw cut necessary destroys the tissues in the area. When the further two cuts along a proximal/distal line are made in order to allow the two pieces of cut bone to be opened out to form the "window" there is again severe damage to the soft tissue and this can severely effect the healing process when the window is subsequently closed.

The present invention is intended to provide apparatus which can be employed with a technique which will not only avoid damage to the soft tissue but enable the "window" to be more easily closed.

The apparatus according to the invention can also be used with apparatus for performing the remainder of the transfemoral osteotomy.

There are obvious difficulties in assessing the particular angular position of the prosthesis in the femoral canal and the exact location of the resectioning of the femur must be accurately judged. A further difficulty arises with regard to the placement of one or more retaining bolts towards the distal end of the stem of the prosthesis. These bolts or pins pass through the bone, the stem of the prosthesis and out through the other side of the bone thus anchoring the prosthesis in position. It is difficult for surgeons to judge the exact position to drill the holes in the bone to coincide with the holes in the implant and it is also necessary to select the correct angular position for the prosthesis and therefore the holes. It is also difficult to judge the exact distance down the femur for the holes to achieve the correct leg length of the correction.

This apparatus for use in performing transfemoral osteotomy is intended to overcome some of the difficulties referred to above and the present apparatus can be used in conjunction with it.

According to the present invention apparatus for use in resectioning a femur when performing transfemoral osteotomy surgery comprises a drill guide element which includes a line of drill openings each of which is adapted to guide a drill and means for securing said drill guide element to a femur to be resectioned with the line of openings extending in a proximal/distal direction.

The apparatus can be used by securing the drill guide element to the femur and drilling through the line of openings to provide an interrupted cut along the bone. Because the drill passes through the soft tissue it is not completely cut but merely has a series of perforations along its length. Prior to drilling the line of holes in the bone the first proximal/distal saw cut will have been made along the top and the longitudinally extending portion of bone can now be broken away along the line of drill holes. The soft tissue is however still in existence between the remainder of the femur and the separated portion so that it can hold the folded back separated portion in place alongside the remainder of the femur and it also provides anchorage

when the window is closed. The same technique is used on the other side of the femur so that a completely open window exposing the femoral canal is produced.

It will be appreciated that the first cut to be made is the transverse cut which provides an exposed end from which the "window" extends in a proximal direction.

Preferably means are included for altering the angular position of the drill guide element on the femur about a proximal distal axis after it has been secured thereto thus enabling accurate placement of the holes. In order that both sides of the opening can be drilled without readjustment of the apparatus the drill guide element can include two parallel lines of drill openings.

Adjacent drill openings can be angled in relation to each other so that the openings are more closely spaced apart on the outer side of the element than on the inner side adjacent the femur and preferably each of the entry points of the openings on the outer side of the element serves two or more openings so that there are more entry points for openings on the inner side of the element than on the outer side. This enables a row of closely spaced openings to be drilled on each side.

The drill guide element can also include means for guiding means for exposing the femur along a proximal distal line. This can be in the form of a guide slot through which the surgeon can open the soft tissue and subsequently saw the first longitudinally extending cut in the bone after it has previously been cut transversely.

The drill guide element may conveniently be removably connected to the securing means to assist in sterilization and so that the securing means can be used in other apparatus.

Preferably the means for securing the element to the femur is in the form of an adjustable open jawed clamp adapted to partially

surround the femur with which it is to be used.

Means can also be included for locating the securing means on a partially resectioned transverse end of the femur after the first transverse cut has been made.

Because of the particular design of the securing means it can also be used in other apparatus for use in performing transfemoral osteotomy.

Thus, when the drill guide element is removed the securing element can be attached to apparatus as set out in the Applicant's co-pending British Patent Application No. GB-A- filed on the same day as the present Application. With this arrangement the securing means acts for securing a support element provided with a drill guide to a prosthesis to be implanted and to a resectioned femur, and means for adjusting the angular position of the drill guide in relation to the resectioned femur about a proximal distal axis.

Thus, this apparatus which incorporates the securing means set forth above can be used to accurately locate the angular position of the drill guide on the prosthesis (anteversion setting) which can be used to drill the holes to take the retaining bolt or bolts in the bone. Preferably the support element includes means for connection to the proximal end of the femoral prosthesis and means can be provided to indicate the angular position of the drill guide relative to the resectioned femur.

Thus, after careful X-ray examination, the precise anteversion setting can be decided and this can then be transferred to the apparatus thus ensuring the correct angular position.

This apparatus can also include means for adjusting the support element to accommodate alternative leg lengths. In order to do this means can be included to vary the proximal/distal position of the support element in relation to the prosthesis securing means.

The support element is preferably in the form of an L-shaped frame one arm of which carries the drill guide and the femur securing means and the other arm carrying the means for connection to the femoral prosthesis which is to be implanted.

With this arrangement the femur securing means which has already been used in opening the "window" can be connected to the L-shaped frame by a bracket which should be adjusted in proximal/distal directions on the frame and in relation to which the securing means can be angularly adjusted about a proximal/distal axis.

The present invention can be performed in various ways but one embodiment will now be described by way of example and with reference to the accompanying drawings in which :

Figure 1 is a diagrammatic side view of a femur showing how it is cut for performing transfemoral osteotomy surgery;

Figure 2 is a diagrammatic perspective view showing how the "window" is formed in the femur for transfemoral osteotomy surgery;

Figure 3 is an end elevation of means for securing a drill guide element to a femur according to the present invention;

Figure 4 is a side elevation of the device shown in Figure 3 attached to the drill guide element of the present invention;

Figure 5 is a plan view from above of the drill guide element shown in Figure 4 in part cross-section on the line V-V of Figure 4;

Figure 6 is an end view of the drill guide element shown in Figure 5;

Figure 7 is a diagrammatic isometric view of apparatus for performing transfemoral osteotomy and incorporating the supporting means shown in Figures 3 and 4; and,

Figure 8 is a part cross-sectional view of means for securing the support element of the apparatus shown in Figure 7 to a prosthesis to be implanted.

Figures 1 and 2 show, in simplified form, how transfemoral osteotomy surgery is performed. The soft tissue indicated by reference letter T in Figure 2 is exposed along a proximal/distal line indicated by chain line L in Figure 2. The soft tissue T is folded back on each side to expose the femur 6 and the bone is resected with three cuts along the same line L with side cuts M and with a transverse cut C. The proximal end of the femur is now opened, as shown in Figure 2, as a "window". From Figure 2 it will be seen that an upper quarter 48 is now laid on each side of the remaining part of the bone to expose the bone canal into which the prosthesis is to be inserted.

The present invention relates to apparatus for use in performing this part of the operation and comprises means 5 for securing a drill guide element 100 to a femur 6. This device has a main body portion 30 on which is located a movable clamping jaw 31. The upper part of the clamping jaw 31 has a screw threaded bore 32 which has a threaded member 33 one end of which carries an operating handle 34 and the other end of which is rotatably housed in the body 30. Thus, rotation of the handle 34 raises and lowers the clamp 31 which is also located by a retaining screw 35 which passes through a slot 136.

The lower end of the open jawed clamp is formed as a pair or curved tines 36 which are adapted to extend around the resectioned femur to which the device is to be clamped.

Guide means in the form of a disc 38 mounted on body 30 are provided, the disc projecting below the lower end 39 of the body 30.

A boss 17 is located in a slot 40 in the body 30 and is held by a nut 37 so that the position of the drill guide element 100 can be adjusted to alter the radial distance from the femur 6.

The drill guide element 100 comprises a semi-circular support 101 connected to a location bracket 102. This bracket 102 has a slot 103 through which the end of the boss 17 can extend, the bracket being held in position by the nut 16.

The surface of the bracket 102 is carried with graduations 104 to indicate the relative angular position between the two parts.

The drill guide element 100 includes a line of drill openings 106 along each side and which are adapted to guide a drill, the line of openings extending in a proximal/distal direction. Two parallel lines of drill openings are provided.

Adjacent drill openings 106 are angled in relation to each other and as will be seen from Figure 5 each of the entry points 107 on the outer side of the element serves three openings on the inner side of the element so that there are more entry points or openings on the inner side of the element than there are on the outer side. This enables a row of closely spaced openings to be drilled on each side.

Means for guiding means for exposing the femur along a proximal/distal line are also provided in the form of a guide slot 110 through which the surgeon can open soft tissue and subsequently saw the first longitudinally extending cut in the bone 6 after it has been previously transversely cut.

The apparatus according to the present invention is used for resectioning a femur when performing transfemoral osteotomy in the following manner. The surgeon first makes a transverse cut C to

expose a proximal end of the femur which can be used as a reference point. This reference point end is exposed by the surgeon and the means for securing the drill guide element to the femur, that is the clamp 5, is placed in position by sliding the tines 36 around the bone ensuring that the guide disc 38 is close up against the severed end indicated by reference numeral 49. As mentioned above, the positioning is achieved with a rotative movement. Once in place the handle 34 is operated to close the clamp and maintain it in place. The drill guide element 100 is now placed and locked in position by nut 16. The element extends over the femur and the surgeon now opens the upper part of the femur by severing the soft tissue through the slot 101. This exposes the femur beneath it so that the surgeon can cut a proximal/laterally extending slot. The surgeon now drills a series of holes using the drill guide means through the soft tissue and into the bone. The row of holes in the bone provides a row of perforations which can be easily broken away to provide the side cuts M but leaving the two broken away parts of the bone still attached to the remainder by the soft tissue in the manner shown in Figure 2.

The "window" now obtained can be used for the remainder of the operation and leaves the femur ready to receive the prosthesis.

Prior to opening the bone the drill guide element 100 will, of course, have been removed by releasing the nut 16 but the securing means in the form of the clamp 5 can be left in position. The same clamp is now used during the remainder of the operation to act as means for securing a support element provided with a drill guide to a prosthesis to be implanted and to a resectioned femur, and means for adjusting the angular position of the drill guide in relation to the resectioned femur about a proximal/distal axis.

This apparatus is shown in Figures 7 and 8 and comprises a support element 1 is in the form of an L-shaped frame having a first arm 10 and a second arm 11. The first arm 10 carries the drill guides 2 and the femur securing means 5 and the second arm 11 carries the means 3 for connecting the proximal end of the femoral prosthesis 4.

The femur securing means 5, as described in Figures 3 and 4, is connected to the first arm 10 by an adjustable bracket 12 which can be adjusted in proximal-distal directions only in a slot 13 in the arm 10 and locked in position by a retaining nut 14, and the femur securing means 5 can be angularly adjusted in relation to the bracket 12 in a slot 15 provided on the bracket and locked in position by the nut 16.

The means 3 for connecting the support element 1 to the femoral prosthesis which is to be implanted is shown in more detail in Figure 8 and comprises a sleeve 20 secured to the second arm 11 and in which is located a securing stud 21.

The proximal end 22 of the femur 4 is provided with a screw threaded bore 23 in which a screw threaded portion 24 of the stud 21 can be located. The other end of the stud is held by a nut 25.

The distal end of the sleeve 20 is provided with a pair of opposed projecting keys 26 which engage in keyways 27 in the form of slots provided in an enlarged end portion of the bore 23.

Thus, it will be seen that the prosthesis 4 can be held in position on the arm 11 and is restrained against relative rotation by the keys 26 and keyways 27.

With the boss 17 located in the slot 40 in the body 30 of the clamp and held by a nut 37 the position of the clamp can be adjusted in relation to the adjustment bracket 12 to alter the radial distance from the femur 6.

The drill guides 2 are carried on the arm 10 by a clamping plate 40 which is held in place by a screw threaded shaft 41 retained by a nut 42. The shaft 41 passes through one of a series of four openings 43 in the arm 1. As will be seen, once the guides have been fixed in position there is a predetermined distance from the guides to the means 3 for connecting the support element 1 to the femoral prosthesis 4. This distance can however be adjusted by using the

alternative openings 43. The drill guides 2 are set for a position with respect to the given prosthesis so that they are fixed and aligned with the holes 44 in the prosthesis 4.

A typical drill bit 45 is shown in place in one of the drill guides 2 and its lower operative end 46 indicates how it has been drilled through the femur 6 passing through the existing holes 44 in the stem 47 and through the other side of the femur 6.

In Figure 7 the bone and soft tissue T, which has been folded back to provide the "window" and expose the femur 6, is indicated by broken lines 48.

To carry out the surgery relating to a transfemoral osteotomy the surgeon first ensures that appropriate X-rays have been taken so that he can consider the amount of bone which needs to be removed from the femur. Once having decided this the measurements are carefully taken for further use with the apparatus according to the invention.

The soft tissue is now opened using the clamped drill guide element as described above to reveal the femur and the bone is cut appropriately to provide a proximal end C, indicated by reference numeral 49 in Figure 7. The "window" is now opened using the clamp and drill guide element as described above. The stem 47 of the prosthesis 4 is now inserted in the femoral canal and the frame in the form of the arms 10 and 11 is connected to it by means of the securing means 3.

The nut 14 is released to allow the bracket 12 to move in the slot 13 and so that it can be secured to the femur securing means 5 by the boss 17 and nut 16 through the slot 15. The release of the nut 16 allows the slot 15 to be placed on the boss 17 at the appropriate radial distance from the femur prior to subsequent tightening. It will be appreciated that the proximal-distal movement in the slot 13 accommodates the leg length adjustment. The ante/retroversion adjustment is now carried out by revolving the frame about the axis of the prosthesis 4 and the particular angle adjustment is set by

tightening the nut 16. During this angular movement the prosthesis 4 which is securely attached to the support frame revolves with it as do the drill guides 2.

The proximal-distal positioning of the drill guides is set according to the pre-operative planning and they are now positioned by releasing the nut 42 so that they can be located in contact with the cortex of the femur and the nut suitably tightened.

The drill guides can now be used to produce the necessary holes through the bone to accept the required bolts or pins.

In the arrangement described above two drill guides are shown but only one or any other number can be utilised if required.

The apparatus can be simply removed by releasing the stud 21 in the prosthesis 4, releasing the nut 16 and removing the frame. The clamp 6 can be removed separately.

The "window" is now closed according to any known post-operative technique.

THIS PAGE BLANK (USPTO)

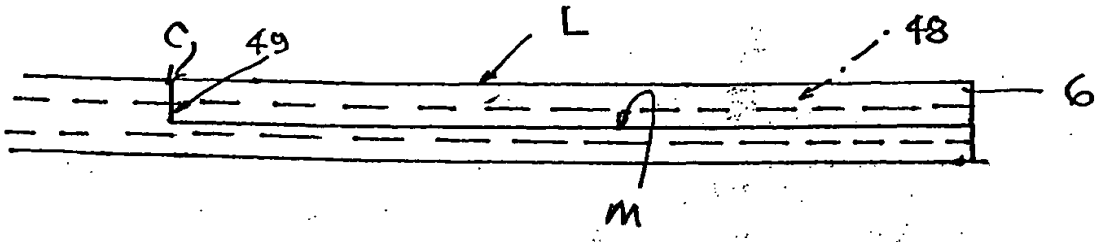
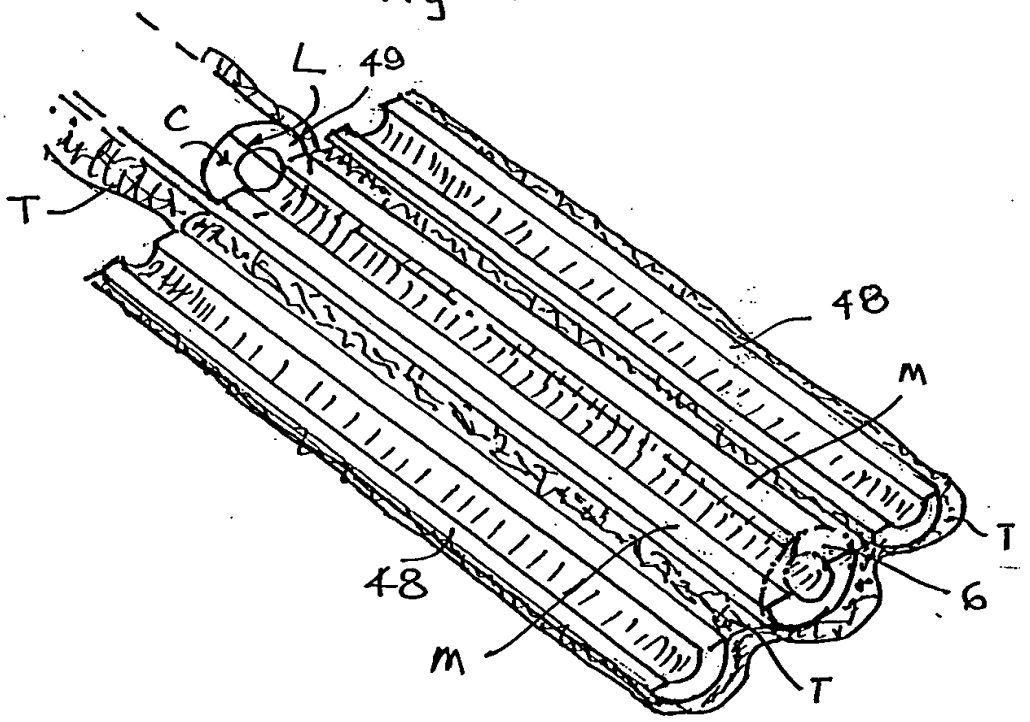


Fig 1

Fig 2



THIS PAGE BLANK (USPTO)

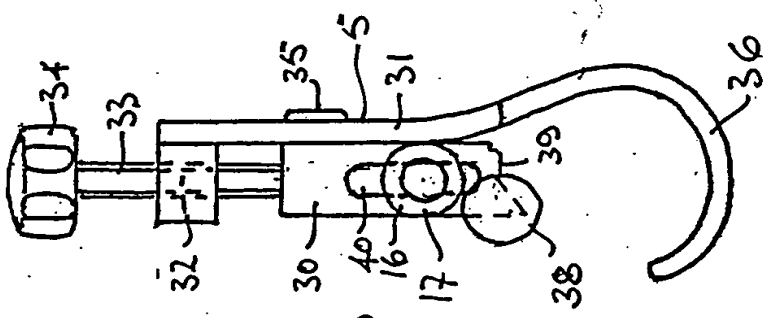

34
33
32
5
35
31
36
39
30
40
16
17
38

Fig 3

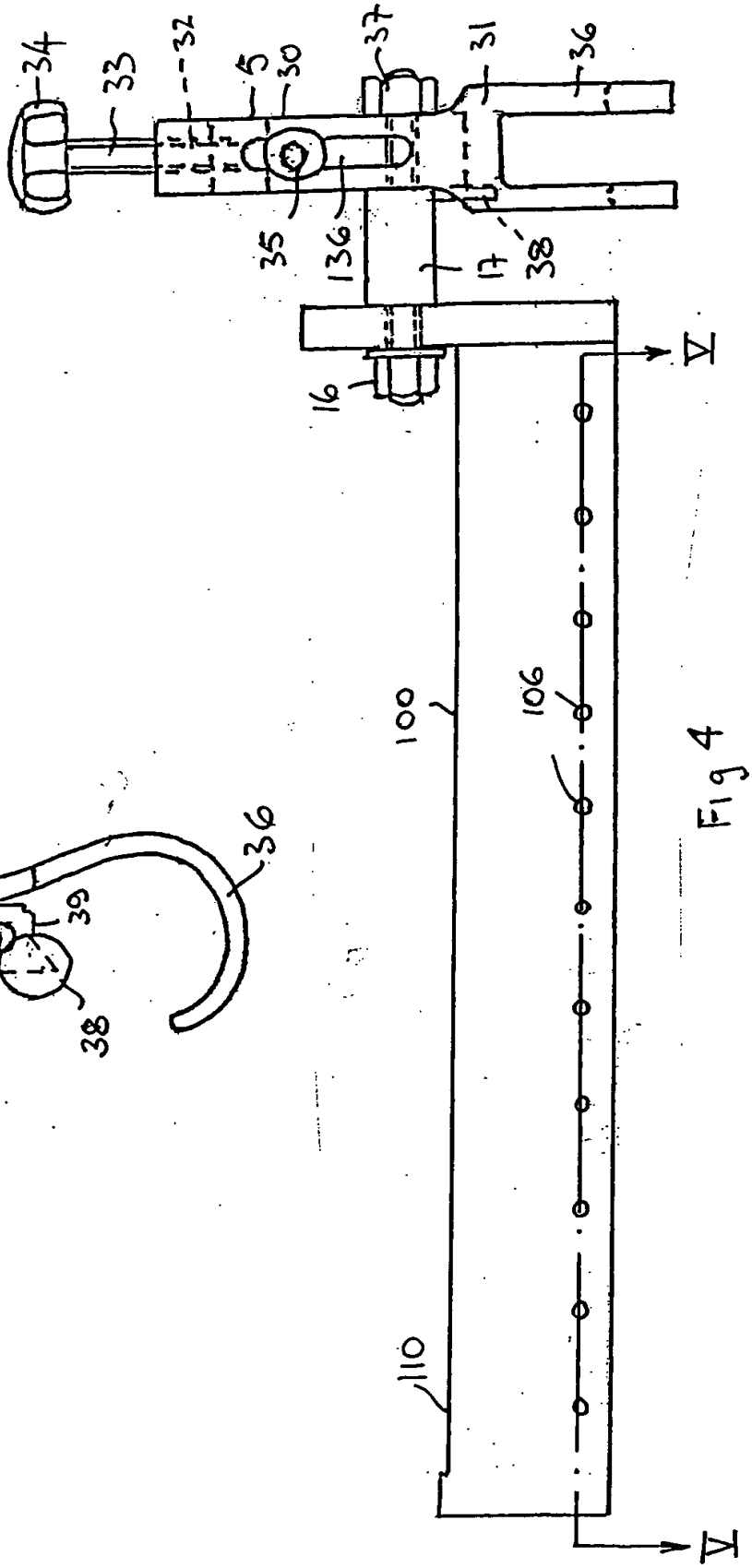

34
33
32
5
30
37
31
36
35
136
17
38
16
V
100
106
110
V

Fig 4

THIS PAGE BLANK (USPTO)

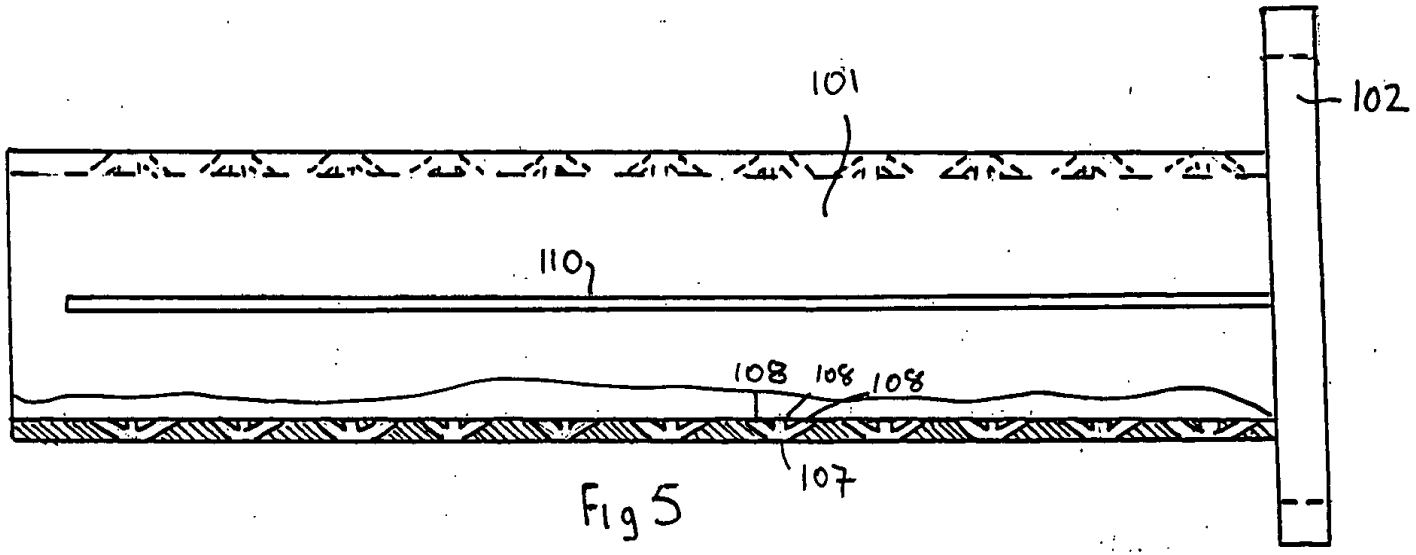


Fig 5

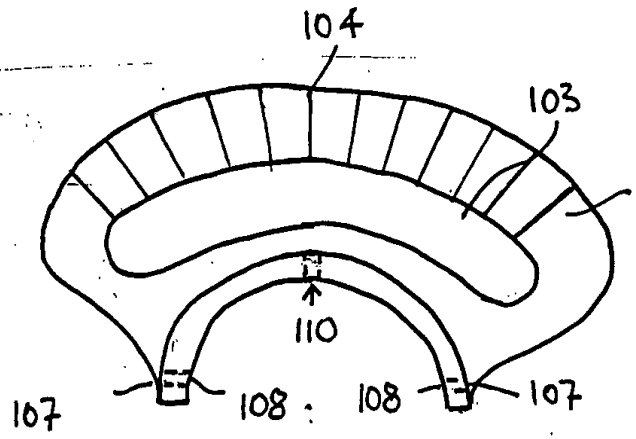


Fig 6

5b

THIS PAGE BLANK (USPTO)

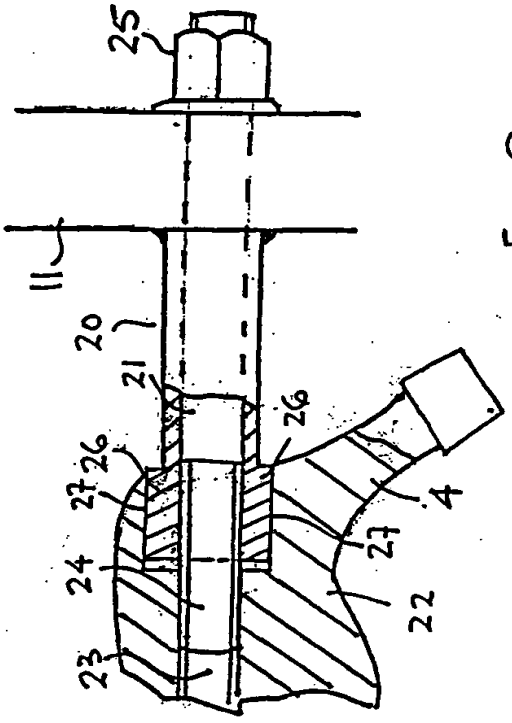
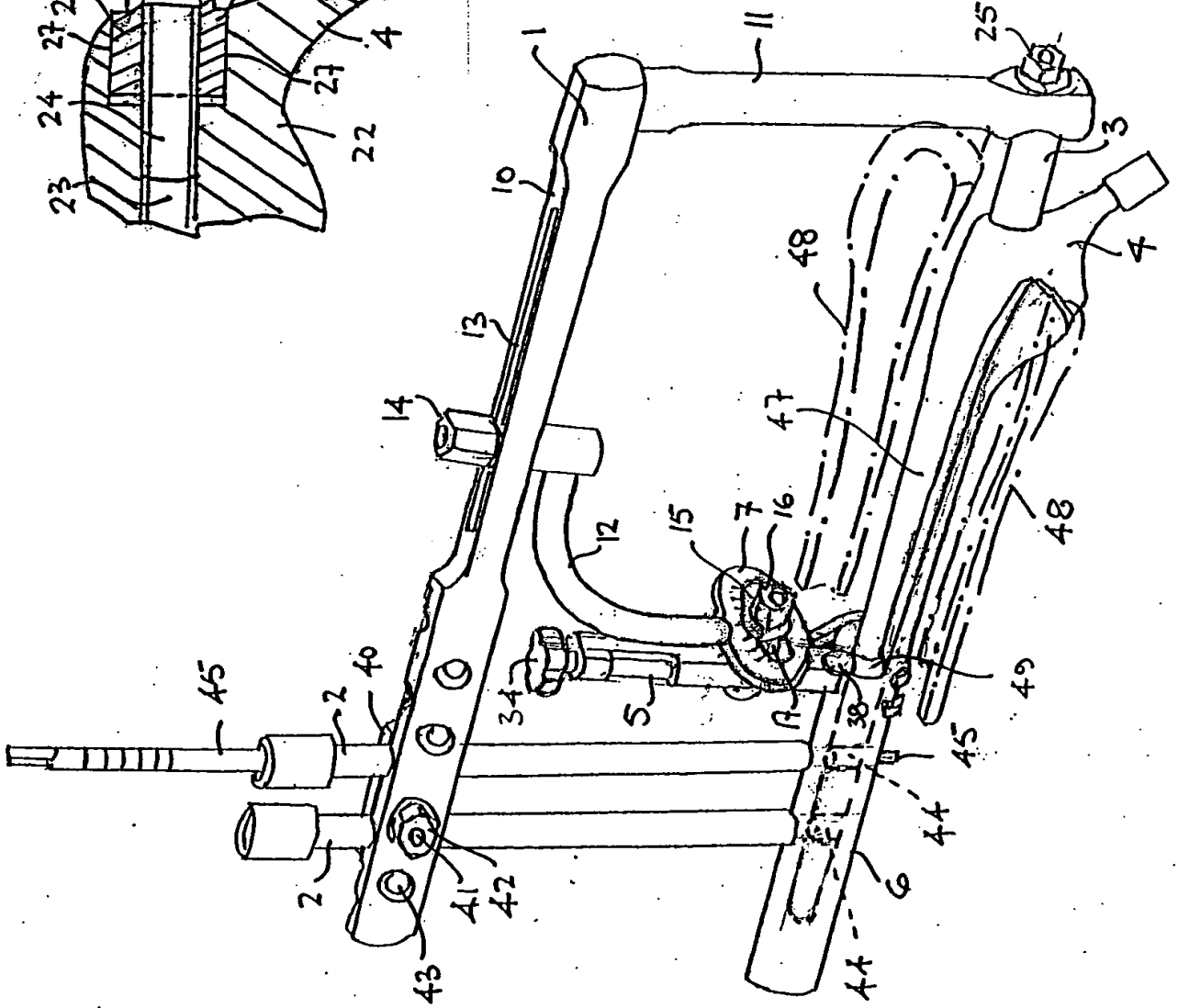

25
11
20
21
26
27
24
23
22
4

Fig 8

Fig 7


1
11
25
3
4
10
48
13
14
47
12
15
7
16
49
34
5
38
45
2
40
41
42
43
44
6

THIS PAGE BLANK (USPTO)